Long-Acting Cabenuva Works Well for Adolescents With HIV

The injectable regimen maintained viral suppression through 96 weeks, and most teens preferred it over daily pills.

March 25, 2026 By Liz Highleyman

Cabenuva (injectable cabotegravir plus rilpivirine), the longest-acting complete antiretroviral regimen, maintained viral suppression for 96 weeks in a study of adolescents in five countries, according to research presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2026). What's more, most participants said they preferred the every-other-month injections over daily pills.

Oral antiretroviral therapy is highly effective, but some people find it inconvenient to take daily pills or don't want to be reminded of HIV every day. This could be especially critical for adolescents, who may struggle more with adherence.

"Adolescents living with HIV often face unique developmental, social and adherence challenges, so the dosing flexibility and freedom offered by long-acting injectables is especially important," said presenter Aditya Gaur, MD, of St. Jude Children's Research Hospital in Memphis, in a ViiV Healthcare news release.

Cabenuva combines an extended-release formulation of ViiV's integrase inhibitor cabotegravir and an injectable version of Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine. Indicated as maintenance therapy for people who have achieved viral suppression on standard oral treatment, it consists of two intramuscular injections administered by a health care provider, usually in the buttocks.

The Food and Drug Administration initially approved Cabenuva as a once-monthly regimen for adults with HIV in January 2021, later adding an every-other-month option. In March 2022, the agency extended the approval to adolescents ages 12 to 17 who weigh at least 77 pounds. (Injectable cabotegravir alone for pre-exposure prophylaxis, sold as Apretude, was approved for both adults and adolescents in December 2021.)

Cabenuva's approval was supported by the ATLAS study, which showed that adults with HIV who switched from a standard oral regimen to monthly injections were about as likely to maintain viral suppression as those who stayed on daily pills. The ATLAS-2M study showed that injections every

two months were comparably effective. The FLAIR trial found that Cabenuva is also effective for adults starting HIV treatment for the first time, though it is not yet approved for this indication.

At CROI, Gaur presented the latest results from the Phase I/II MOCHA (More Options for Children and Adolescents) trial, also known as IMPAACT 2017. This analysis included 144 adolescents ages 12 to 17 in the United States, Thailand, Botswana, South Africa and Uganda. More than 90% acquired HIV via mother-to-child transmission. Boys and girls were equally represented, about three quarters were Black and the median age was 15 years. At study entry, they were on standard oral antiretroviral therapy with an undetectable viral load (below 50).

Participants switched from their oral regimen to cabotegravir and rilpivirine pills for four weeks before starting injections. The first two shots were given one month apart, and the dosing interval was thereafter lengthened to every two months. There was no control group for comparison.

Gaur reported results from a planned analysis at 96 weeks as well as an end-of-study analysis that included a subset of 117 teens who received Cabenuva in a study extension for up to 48 more weeks until they could obtain it from other sources. Most participants (95%) remained on the study for 96 weeks or longer and received at least 13 injections. Almost all got their injections within eight days of the target date.

Most participants (94%) maintained viral suppression at 96 weeks. Eleven people had at least one viral blip, but none had confirmed virological failure with two consecutive viral load measurements above 200. A pharmacokinetic analysis showed that cabotegravir and rilpivirine levels were comparable to those seen in adults.

Cabenuva was safe and generally well tolerated, though 42% of participants experienced drug-related adverse events. The most common side effect, reported by 37%, was injection site reactions, such as pain, redness or swelling. These were usually mild to moderate, lasted no more than a week and decreased over time. Transient postinjection reactions (symptoms such as shortness of breath, cramping, dizziness or changes in blood pressure) were rare. Three participants (2%) had severe (Grade 3 or higher) adverse events: two abscesses and one case of anaphylaxis.

Acceptability and tolerability were assessed throughout the study. Despite reporting variable levels of pain, more than 97% of participants said they preferred the long-acting injections over daily pills at all time points.

“In IMPAACT 2017, every adolescent who expressed a preference after almost two years of treatment chose the injectable regimen over daily pills,” Gaur said. “For many, it was the first time in their lives they did not have to take an oral HIV medicine every day, and moving to a brief clinic visit every two months can help reduce daily reminders of HIV.”

Researchers also presented interim results from the ongoing Phase I/II IMPAACT 2036 (CRAYON) trial, the first study to test Cabenuva in children ages 2 to 11 years. Pharmacokinetic and safety data look promising so far, suggesting that long-acting injectable treatment could one day be an

option for kids as young as 2 years.

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